



Contact:
Jim Ronca
Michael Monheit
Greg Spizer
Michael Schafle
Anita Pitock

Email:
jronca@anapolschwartz.com

Toll Free: (866) 735-2792

Read more information online at:
www.anapolschwartz.com

© 2011 All Rights Reserved.

MEDICAL DISCLAIMER: This PDF is not designed to and does not provide medical advice, professional diagnosis, opinion, treatment or services or otherwise engage in the practice of medicine, to you or to any other individual. Please use this information to help in your conversation with your physician. This is general information and always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition. Never disregard or delay seeking professional medical advice or treatment because of content found in the PDF, website, or newsletter.

RESEARCH AND RECENT STUDIES:

Causes of Cleft Lip and Palate: SSRIs

CONTENTS

What are SSRIs?	2
What birth defects are associated with SSRIs?	2
PPHN / persistent pulmonary hypertension of the newborn	2
Congenital heart defects, ASD, VSD	3
Cleft palate and cleft lip	3
Omphalocele	3
What are alternative drugs and treatments? Are there safer drugs?	4
Short summary of studies about SSRI risks for pregnant women:	4
Do you have more questions?	5
References	5

ATTORNEY DISCLAIMER: This PDF is dedicated to providing general public information regarding legal rights. None of the information on this PDF is intended to be formal legal advice, nor the formation of a lawyer or attorney client relationship. Please contact a Lawyer for information regarding your particular case. This PDF is not intended to solicit clients outside the states of Pennsylvania, New Jersey, Ohio, West Virginia and Arizona.



WHAT ARE SSRIS?

Selective serotonin reuptake inhibitors are a class of compounds typically used as antidepressants for the treatment of depression, anxiety disorders, and some personality disorders.

Some brands of SSRIs include Paxil, Prozac, Wellbutrin, Zoloft, Lexapro, Celexa, Cymbalta, Effexor, Remeron, and Symbyax, to name a few.

SSRIs block the reabsorption of the neurotransmitter serotonin in the brain. Changing the balance of serotonin seems to help brain cells send and receive chemical messages, which in turn boosts mood. SSRIs are called selective because they seem to primarily affect serotonin, not other neurotransmitters.

WHAT PRESCRIPTION DRUGS ARE SSRI MEDICATIONS?

SSRI drugs include the following: Celexa, Cymbalta, Effexor, Lexapro, Paxil, Prozac, Remeron, Symbyax, Wellbutrin, Zoloft. Formulations of SSRI medications are offered by a number of different pharmaceutical manufacturers.

WHO MAKES SSRIS?

Celexa—Forest Laboratories

Cymbalta—Lilly

Effexor—formerly Wyeth Laboratories/now Pfizer

Lexapro—Lundbeck/Forest Laboratories

Paxil—GlaxoSmithKline

Prozac—Lilly

Remeron—Organon

Symbyax—Lilly

Wellbutrin—GlaxoSmithKline

Zoloft—Pfizer

WHAT BIRTH DEFECTS ARE ASSOCIATED WITH SSRIS?

The most common birth defects are heart defects, cleft lip and cleft palate, Down syndrome and spina bifida.

SSRIs are not considered major teratogens. However, they cross the placenta and may affect your newborn. Zoloft and Paxil and the SSRI as a group have been associated with congenital malformations, particularly septal defects.

PPHN / PERSISTENT PULMONARY HYPERTENSION OF THE NEWBORN

A recently published case-control study has shown that infants born to mothers who took SSRIs after the 20th week of pregnancy were six times more likely to have persistent pulmonary hypertension (PPHN) than infants born to mothers who did not take antidepressants during pregnancy. PPHN is a life-threatening disorder in which the newborn's arteries to the lungs remain constricted after delivery, limiting the amount of blood flow to the lungs and therefore the amount of oxygen into the bloodstream.

The background risk of a woman giving birth to an infant affected by PPHN in the general population is estimated to be about 1 to 2 infants per 1,000 live births. Neonatal PPHN is associated with significant morbidity and mortality.

SSRIs brands that affect PPHN include Celexa, Fluvoxamine, Lexapro, Paxil, Prozac, Symbyax, and Zoloft.



CONGENITAL HEART DEFECTS, ASD, VSD

The Food and Drug Administration (FDA) has determined that [exposure to paroxetine, Paxil, Paxil CR, and Pexeva in the first trimester of pregnancy](#) may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer GlaxoSmithKline changed Paxil's pregnancy category from C to D and added new data and recommendations to the "Warnings" section of the prescribing information.

Most of the cardiac defects observed in these studies were atrial septal defects (ASD) or ventricular septal defects (VSD), conditions in which the wall between the right and left sides of the heart is not completely developed.

Wellbutrin, a popular antidepressant, has been linked to heart-related birth defects for women who took the drug one month prior to getting pregnant and during the first trimester of pregnancy.

CLEFT PALATE AND CLEFT LIP

There was also a notable rise in facial malformations such as cleft lip and palate. A cleft is a gap resulting from an incom-

plete closing of a structure during development. Clefts that occur in the lip and palate or roof of the mouth are called oral-facial clefts. Some babies only have a cleft lip. Many babies who have cleft lip also have a cleft palate. Cleft palate also can occur without cleft lip.

OMPHALOCELE

[Omphalocele is a congenital defect in the abdominal wall](#) in which variable amounts of abdominal contents protrude into the base of the umbilical cord. Until about week 10 of pregnancy, it is normal for the bowel to be outside of the baby's belly. After 10 weeks the bowel or intestines should be inside the belly.

According to the Centers for Disease Control and Prevention ([CDC](#)) about 775 babies in the United States are born with an omphalocele per year.

One of the causes of [omphalocele](#) is taking SSRIs during pregnancy. Some brands of SSRIs include Paxil, Prozac, Zoloft, Lexapro, Celexa, Asentra.





HOW MANY PEOPLE TAKE SSRIS?

According to an August 2009 article in USA Today, about 10% of Americans—or 27 million people—were taking antidepressants in 2005, the last year for which data was available at the time the study was written. That’s about twice the number in 1996, according to the study of nearly 50,000 children and adults in today’s *Archives of General Psychiatry*. Yet the majority weren’t being treated for depression. Half of those taking antidepressants used them for back pain, nerve pain, fatigue, sleep difficulties, or other problems.

WHAT ARE ALTERNATIVE DRUGS AND TREATMENTS? ARE THERE SAFER DRUGS?

Because of the concern for SSRIs and birth defects, guidelines were released last year by the [American Psychiatric Association](#) and the [American College of Obstetricians and Gynecologists](#) stating that psychotherapy may be an effective alternative to antidepressants for pregnant women with mild to moderate depression.

However, the guidelines say, women with a history of more severe depression, or other major psychiatric disorders, may need to continue with their medication.

Also while antidepressants may be covered by health insurance, psychotherapy or psychiatry is usually not.

SHORT SUMMARY OF STUDIES ABOUT SSRI RISKS FOR PREGNANT WOMEN:

► [In the fall of 2005, GlaxoSmithKline released some information](#) from their recently collected safety data indicating an increased risk of major congenital malformations among in-

fants exposed during organ development to Paxil. Among 527 fetuses exposed to Paxil in the first trimester, 23 were born with major congenital malformations. Most of the malformations were cardiovascular, and the majority of those were ventricular septal defects (VSD). As compared with infants born to women taking any other antidepressant agent during the first trimester, the adjusted odds ratio for any malformation was 2.2, 1.3 to 3.6. Previously published studies were generally smaller and had not produced clear evidence.

- Boston: The Slone Epidemiology Center at Boston University, the Genetics Unit, Massachusetts General Hospital for Children, and the Department of Epidemiology, Harvard School of Public Health assessed associations between first-trimester maternal use of SSRIs and the risk of birth defects among 9,849 infants with and 5,860 infants without birth defects participating in the Slone Epidemiology Center Birth Defects Study. Among outcomes previously reported to be associated with SSRI use, there were 127 cases of omphalocele, 115 cases of craniosynostosis, and 3,724 cases of congenital heart defects.
- A SSRI used in combination with benzodiazepines (examples are valium, Librium, Xanax, Atavan, etc.) increased the risk of Congenital Heart Disease (CHD) by 1.19 percentage points compared with no exposure. The risk difference remained statistically significant. SSRI alone (or monotherapy) did not increase the risk overall when compared with no exposure. The risk for ventral septal defect (VSD) did not increase with poly-drug exposure while the risk for atrial septal defect (ASD) increased with using SSRIs alone.
- Clinical trials are not practiced on pregnant women. Data is culled from pregnancy registries. In 6 of 7 studies comparing developmental outcomes of children exposed to antidepressants in utero with non-exposed children reported no significant differences. Most of these antidepressant medications

remain relatively safe in pregnancy, but some significant areas of concern exist—particularly some evidence of higher risk of preterm birth, neonatal adaptation difficulties and congenital cardiac malformations (with Paxil).

DO YOU HAVE MORE QUESTIONS?

Cleft lip or palate is one of the most common birth defects, currently affecting one in 600 children in the United States. Do you want more information about cleft lip and palate or SSRIs? Do you question as to whether the SSRIs you were prescribed could be related to your child's cleft lip and cleft palate? Please [contact us](#) for assistance.

SHOULD I FILE A LAWSUIT?

It's quite possible that you should and here's why: Your baby may require expensive procedures that health insurance will most likely not cover or not cover in their entirety. There will be ongoing therapy, costly care giving, and numerous prescription drugs. If employed or self employed, you may need to take time off work. You, your family, and your baby's pain and suffering will be all consuming. A [lawsuit](#) can help pay for medical bills and expenses.

When is the best time to file a birth defect lawsuit?

The sooner the better—it takes time to compile information and hospital records. Every state has what is called statute of limitations and places limits on how long the injured party can wait to file a lawsuit. The last thing you want to do is lose that opportunity to file. That would be considered reckless behavior.

What is the statute of limitations to file a lawsuit?

In Pennsylvania, New Jersey, and West Virginia, a personal injury lawsuit must be filed within two years of the date when the injury occurred.

How much does it cost to file a lawsuit?

Clients pay no out-of-pocket expense and only pay if and when their settlement is received. A settlement affords you compensation for mounting medical bills, caregivers, loss of income (if still working), and pain and suffering.

Who is Anapol Schwartz?

Anapol Schwartz upholds traditions of excellence in [medical malpractice](#), pharmaceutical, toxic tort, class actions, products liability, and automobile accident litigation. Law offices are located in Pennsylvania, New Jersey, West Virginia, Arizona, and of Counsel in Ohio.

REFERENCES

- Food & Drug Administration Safety Alerts, SSRIs and Treatment Challenges of Depression in Pregnancy, July 2006
- March of Dimes/about birth defects
- Food & Drug Administration Alerts, increased risk of neonatal persistent pulmonary hypertension, July 2006
- Food & Drug Administration, Public Health Advisory: Paroxetine, 12/8/2005
- New England Journal of Medicine 356:26, June 28, 2007; Teratogenicity of SSRIs—Serious Concern or Much Ado about Little? By Michael F. Greene, M.D.
- New England Journal of Medicine 2007; 356:2675-83, First-Trimester Use of Selective Serotonin-Reuptake Inhibitors and the Risk of Birth Defects, By Carol Louik, Sc.D., Angela E. Lin, M.D., Martha M. Werler, Sc.D., Sonia Hernández-Díaz, M.D., Sc.D., and Allen A. Mitchell, M.D.
- Birth Defects Research, Part B, 83:68-76, 2008, Major Congenital Malformations Following Prenatal Exposure to SSRIs and Benzodiazepines Using Population-Based Health Data
- Antidepressants in pregnancy: a systematic review; NCBI; Australian New Zealand Journal of Psychiatry; 2010 Nov;44 (11):978-96.